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FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
PANDE, SUCHIRA	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/791,502	KRAMER ET AL.
	Examiner	Art Unit
	Suchira Pande	1637

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2/07*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. Amendment filed on April 3, 2007 is acknowledged. Claims 1-16 were pending in the application. With the amendment Applicant cancelled non-elected claims 1-8. Applicant also cancelled examined claims 9-16. Applicant added new claims 17-37. Currently claims 17-37 are pending and will be examined in this action.

Drawings

2. Examiner thanks Applicant for bringing the drawings submitted on August 9, 2004 to her attention. These drawings are acceptable. Accordingly the objection to drawings raised in previous office action is withdrawn.

Specification

3. The amendment to specification is acceptable and overcomes the objections raised in previous office action. Accordingly the objection to specification is withdrawn.

Claim Objections

4. Cancellation of claim 9 and replacement by independent claim 17 overcomes the objection to claim 9 raised in previous office action.

<u>Response to arguments against rejection over Bruchez, Jr. et. al. (US Pat. 6,500,622) in view of Bonnet et. al. 1999 under 103(a)</u>

5. Applicant's arguments filed on April 3, 2007 have been fully considered but they are not persuasive.

Bruchez et al. in view of Bonnet et al. teach all the components of the recited claims 17. Applicant is arguing how system taught by Bruchez et al.

differs from the claimed invention. Applicant is arguing limitations that are not part of base claim 17. Most of applicant's arguments are drawn to fact that capture probe is different from the signaling hairpin. Examiner would like to point out that there is no requirement in claim 17 that capture probe be different or separate from the signaling hairpin. Therefor the rejection is maintained.

Since Applicant has cancelled the examined claims and presented new claims with different limitations in the base claim. Hence new grounds of rejections are being introduced in this Office Action.

Claim Interpretation

6. The claims are interpreted in the following way: the capture probes are considered to be the signaling hairpins. Applicant has not defined planar and linear array. In absence of any specific requirement following interpretation is being used: An array is distributed on a planar surface hence any array will be a planar array. Furthermore a line is a distance between two points hence any array will have two points so the probes distributed between any two points will represent a linear array.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 17- 22, 24-31, 33-36, and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchez, Jr. et al. (US Pat. 6,500,622 issued Dec 31, 2002) in view of Chee et al. (WO 01/46675 A2 published 28 June 2001, provided by Applicant in the IDS submitted with the amended claims).

Regarding claim 17, Bruchez, Jr. et al. teach:

A hybridization assay (see col. 30, lines 38- 41; col. 38, Example 2 and col. 39 lines 38-44, where hybridization assay is taught) *for at least one of a multiplicity of nucleic acid sequences in an analyte* (see col. 31, lines 31-33 where strategies are taught that will allow multiplexing. See col. 7, lines 42-45 where hybridization to corresponding different target polynucleotide is taught. Specifically see col. 39 lines 58-62 where hybridization assay to monitor much larger number of DNA samples using encoded bead conjugates is taught) *comprising the steps of :*

*a) contacting said analyte with a mixture of encoded microcarriers having immobilized on their surfaces (*see col. 35, lines 32-33 where multiplexed embodiment using creation of two different sets of spectrally encoded beads—referred to as microcarriers in the instant application is taught. see col. 35 lines 40-47 where analyte contact with microcarrier is taught*).* re

(i) a capture probe (see col. 35, lines 6-9, where contacting target sequences with the capture probe and hybridization of target sequence with complementary capture probe sequence is taught.),

*(ii) a coding scheme comprising a plurality (*see col. 7 lines 41-45 Bruchez teaches where plurality of probes conjugated to same substrate. This teaching of Bruchez et al is being interpreted to mean that Bruchez et al. teach plurality of probes attached to surface of same microcarrier*) of signaling hairpins* (see col. 7, lines 7-9 where stem loop structure is taught---another way of saying hairpin. These hairpin in form of molecular beacon is conjugated to fluorophore and quencher moiety hence its capable of signaling the presence or absence of analyte-thus Bruchez et al teach signaling hairpins. See col. 7, lines 40-52 where plurality of probes conjugated to same substrate is taught. See col. 39, lines 39-42, where coded microspheres (microcarriers) conjugated to four different molecular beacons is taught) *comprising quenched, fluorophore- labeled hairpin molecules each comprising an interacting affinity pair separated by a linking moiety, one member of said affinity pair having bound thereto at least one quenched fluorophore and the other member of the affinity pair having bound thereto at least one quencher* (See Fig. 2 where quenched, labeled signaling

hairpin molecule each comprising an interacting affinity pair separated by a linking moiety, one member of the affinity pair having bound thereto at least one fluorophore and the other member of the affinity pair having bound thereto at least one quencher is depicted. Also see col. 3, lines 19-45; col. 21, lines 15-29 and col. 30, lines 26-67 where molecular beacon on a bead is described), *wherein interaction of the affinity pair is disruptable to unquench said at least one fluorophore by a physical or chemical change in a condition of its environment,* (see Fig. 2 right panel where binding of target molecule to hairpin probe (chemical change) disrupts the interaction of the affinity pair of the hairpin molecule resulting in fluorescence signal to be detected. See col. 21 lines 23-29 where hybridization of target to probe leading to fluorescence emission is taught. Also see col. 31, lines 25-30)

wherein the disruption of the interaction of at least one affinity pair occurs at a first level of said condition and the disruption of the interaction of at least another affinity pair occurs at a second level of said condition (see col. 35 lines 9-30 where Bruchez, Jr. et. al. teach binding of two SNP alleles to two capture probes. Here different salt and temperature conditions allow for binding of the two targets to their respective probes, thus Bruchez, Jr. et. al. teach the disruption of the interaction of at least one affinity pair occurs at a first level of said condition and the disruption of the interaction of at least another affinity pair occurs at a second level of said conditions)*, and wherein said disruptions are optically differentiable* (see col. 31, lines 31-40)

and wherein the coding scheme for identifying individual microcarriers in said mixture comprises a combination of multiple spectrally differentiable fluorophores (see col. 24 lines 48-59 where multiple spectrally differentiable fluorophores are taught. See col. 31, lines 30-51 where conjugation to different colors or color combinations for multiplexing are taught) *and multiple affinity pairs disruptable at detectably different levels of said condition* (See col.7, lines 41-52 where plurality of different first polynucleotide or probes—(multiple affinity pairs) are taught and separate binding of each different amplification product to its corresponding probe nucleotide can be detected using a different label on each different amplification product, by the location on the substrate at which each probe polynucleotide is located, or by the conditions under which each amplification product binds, or combinations thereof.---By this broad teaching Bruchez et al. teach multiple affinity pairs disruptable at detectably different levels of said condition

b) forming a distributed array of said microcarriers (see col. 35, lines 55-67 where various methods of preparing microarrays are taught. By teaching method of preparing microarray slides see col. 35 lines 55-56, Bruchez, Jr. et. al. teaches forming a distributed array, which is described by applicant as setting the microcarriers, preferably microbeads, onto a planar surface, for example a microscope slide as a distributed array.

c) determining which microcarriers have capture probes hybridized to nucleic acid sequences of said analyte; (see col. 31, lines 25-30, where Bruchez, Jr. et. al. teach fluorescence is observed as quencher in the capture

probe moves away from the reporter fluorescent moiety as a result of binding of the analyte to the capture probe. To begin with all the microcarriers are non-fluorescent. Only those microcarriers that have target analyte bound to them become fluorescent.) *and*

d) optically decoding the microcarriers having hybridized capture probes to identify said at least one nucleic acid sequence

Bruchez, Jr. et. al. teaches signature of the encoded microspheres (referred to by applicant as microcarriers) is detected to identify the nature of the molecular beacon (term used for the capture probes used in the art to describe the probes used in the current invention). Thus Bruchez, Jr. et. al. teaches decoding of microcarriers to identify the sequences of their capture probes. This decoding is optical is inherent to the detection system and col. 31, lines 41-51 provide explicit support to this conclusion where *Bruchez, Jr. et. al.* teaches use of different region of emission spectrum in the spectral region of interest to encode different microspheres. See col. 35 lines 20-48 where detection of SNP by optically decoding the microcarriers having hybridized capture probes is taught).

Regarding claim 17 Bruchez et al. do not explicitly recite a mixture of encoded microcarriers in step a)

Regarding claim 17, Chee et al, explicitly teach use of a mixture of encoded microcarriers (see Page 4, lines 18-22 and page 5, lines 15-18).

Regarding claim 17, Chee et al, also teach beads containing capture probes (see page 9, line 11).

Regarding claim 21, Chee et al, teach wherein steps (c) and (d) include decoding all microcarriers (see page25 lines 36-39 and page 26 lines1-2 where counting of beads is perfomed to provide positive and negative bead count. This inherently requires that all microcarries be decoded)

Regarding claim 24 and 30, Chee et al, teaches wherein forming the distributed array comprises immobilizing individual microcarriers at the ends of fibers in a fiber-optic bundle (see page 4, lines 2-6)

Regarding claim 25 and 34, Chee et al, teaches wherein steps c) and d) include flow cytometry (see page 23 line 15 where FACS is taught by teaching FACS Chee et al teach wherein steps c) and d) include flow cytometry).

Regarding claims 29 and 35, Chee et al, teaches where distributed array is a planar array. (see page 8, line 26 where planar array is taught).

Regarding claim 36 Chee et al, teaches distributed array. As explained in claim interpretation by teaching a distributed array Chee et al inherently teach a linear array. Also Chee et al. teach sorting of beads by FACS. Here the beads are inherently sorted one after another ie in a linear manner hence the array of beads formed is a linear array.

Regarding claim 18, Bruchez et al. teaches: *wherein said interacting affinity pair comprises complementary oligonucleotide sequences hybridized to one another* (see col. 20 lines 60-62 where first and second complementary sequences hybridization to each other to form a stem is taught. By this teaching Bruchez et al. teaches wherein said interacting affinity pair comprises complementary oligonucleotide sequences hybridized to one another) .

Regarding claim 19, Bruchez et al. teaches *wherein said mixture of signaling hairpins includes at least three affinity pairs* (see col. 6 lines 29-33 where use of 2, 3, 4, 5, 10--- probes is taught. Hence said mixture of signaling hairpins includes at least three probes.

Regarding claim 20, Bruchez et al. teaches *wherein said mixture of signaling hairpins includes from three to eight affinity pairs* (see col. 6 lines 29-33 where use of 2, 3, 4, 5, 10--- probes is taught. Hence Bruchez et al. teaches mixture of signaling hairpins includes at least three to eight affinity pairs).

Regarding claim 21, Bruchez et al. teach *wherein steps (c) and (d) include decoding all microcarriers* (see above as explained for steps (c) and (d) for claim 17 where decoding microcarrier is taught. Since the labels on the signaling molecules are quenchers and fluorescent which are quenched in absence of analyte and in presence of analyte they become fluorescent so steps (c) and (d) inherently require that the instrument (capable of detection change in fluorescence be able to decipher which microcarrier is fluorescing at what wavelength. By teaching flow cytometry for detection (see col. 14 lines 48-49) Bruchez et al. teach wherein steps (c) and (d) include decoding all microcarriers as all the beads are individually interrogated in a flow cytometer a principle routinely used in the art to perform FACS analysis.

Regarding claim 22, Bruchez et al. teach *wherein said linking moiety comprises an oligonucleotide sequence* (see Figure 2 where molecular beacon is taught as a probe this molecule contains linking moiety, which is an oligonucleotide).

Regarding claim 26, Bruchez et al. *teach wherein a quencher is attached to the complementary oligonucleotide sequence not bearing the at least one fluorophore* (See col. 21 line 39-45 where BODIPY is taught as a quenchable dye that is attached to the complementary oligonucleotide sequence not bearing the at least one fluorophore).

Regarding claims 27-28 and 31, Bruchez et al. teach method of claims 18 and 17 including steps a) and b) as described above. Claims 27 and 31 require that step (a) precede step (b) and claim 28 requires that step (b) precede step (a). Base claim 17 has been written using open language comprising. Hence to one of ordinary skill in the art it is obvious as to the order of sequence in which these two steps are conducted. This will depend on the type of assay being conducted. See MPEP 2144.04 IV c. 2144.04 Legal Precedent as Source of Supporting Rationale [R-1]. CHANGES IN SIZE, SHAPE, OR SEQUENCE OF ADDING INGREDIENTS. Changes in Sequence of Adding Ingredients
See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results).

Regarding claim 29, Bruchez, Jr. et al. teach wherein said distributed array is a planar array (see col. 35, lines 56 where microarray slides are taught. Thus by teaching microarray slides Bruchez, Jr. et al. teach planar array).

Regarding claim 31, Bruchez, Jr. et al. teaches *wherein step a) precede step b)*. Bruchez, Jr. et al. teaches use of flow cytometer to read results of molecular beacon on a bead assay (see col. 39, lines 39-62. In the assay

performed step a) contacting said mixture and said analyte precedes detection step.) In the same assay referenced above Bruchez, Jr. et al. teaches the encoded beads could be analyzed using a flow cytometer par.39, lines 56-57). It is well known in the art that flow cytometer can be used to form distributed array of beads in flow cells and it is a device that can be used to detect the signals on each beads. In the assay described the binding of analyte to the beads was done in tubes (batch treatment of beads in a reaction slurry) and 20-30,000 of these treated beads were analyzed. Here no preformed distributed array was used. Therefore the experimental design taught by Bruchez, Jr. et al. inherently requires that step a) precede step b) of forming distributed arrays. See also col. 40 lines 53-58 where beads were batch treated before being read by flow cytometer. Thus Bruchez, Jr. et al. teaches the assay according to claim 17 wherein step a) precedes step b).

Regarding claim 33, Bruchez, Jr. et al. *teach the step of decoding includes disrupting said affinity pair by addition of a denaturant* (see col. 35, lines 9-19 where Bruchez, Jr. et al. teach use of varying salt concentration to optimize disruption of affinity pairs to allow binding of templates differing in single nucleotide polymorphism). Salt is used as a denaturant in this case. Thus Bruchez, Jr. et al. teach the step of decoding includes disrupting said affinity pair by addition of a denaturant.

Regarding claim 37, Bruchez, Jr. et al. teach wherein said capture probe is a molecular beacon probe. (see col. 30 lines 62-63 where attachment of molecular beacons to microspheres is taught)

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Chee et al. in the method of Bruchez et al. at the time the invention was made. The motivation to do so is provided by Chee et al. who state “array compositions that utilize microsphers or beads on a surface of a substrate, for example on a terminal end of a fiber optic bundle, with each individual fiber comprising a bead containing an optical signature------One drawback with the previous system is that it requires a set of unique optical signatures. While large sets of such signatures are available, for example by using different ratios of different dyes, it would be preferable to use decoding systems that do not rely on the use of sets of optical signatures. Accordingly it is an object of the invention to provide methods to allow decoding of bead arrays without relying solely on unique optical signatures” (see page 3 line 39-page 4 lines 1-8)

10. Claims 23 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchez, Jr. et al. (US Pat. 6,500,622 issued Dec 31, 2002) and Chee et al. (WO 01/46675 A2 published 28 June 2001) as applied to claims 17-18 above in view of Bonnet et al. (1999) Proc. Natl. Acad. Sci. vol. 96: pp. 6171-6176 (cited by applicant in the IDS)

Regarding claims 23 and 32, Bruchez et al. teach methods of claims 18 and 17 respectively but do not teach wherein the step of decoding includes disrupting the hybridized affinity pairs by increasing temperature.

Regarding claims 23 and 32, Bonnet et. al. teaches wherein the step of decoding includes disrupting the hybridized affinity pairs by increasing temperature (see Table 1, page 6175 where probe target duplexes containing

three mismatches A-A; C-A; and G-A is taught. The mismatch leads to change in melting temperature for dissociation of probe from target duplex. Perfect match TA has a melting temp of 42°C. While G-A mismatch dissociates at 28°C; A-A mismatch dissociates at 27°C and C-A mismatch dissociates at 23°C. This implies that at those three different temperatures the microcarrier containing those specific DNA molecules will become fluorescent and hence would be identified by Flow cytometery (taught by Bruchez et al see above) instrument capable of performing Fluorescent Activated Cell Sorting (FACS) analysis. Thus Bonnet et al. teaches step of decoding includes disrupting the hybridized affinity pairs by increasing temperature.

It would be *prima facie* obvious to one of ordinary skill in the art at the time of this invention to combine the affinity pairs taught by Bonnet et al. with the affinity pairs taught by Bruchez, Jr. et. al. The motivation to do so is provided by Chee et al. who teach decoding of array sensors with microspheres. Chee et al. teach decoding using pH titration in one embodiment (see page 27 lines 35-39 here optical signatures are generated using pH responsive dyes). Bonnet et al. teach that increasing temperature results in dissociation of strands based on the nature of the mismatch. Thus when temperature probes that dissociate at different temperature are used in the invention of Bruchez et al will result in formation of microcarries (microspheres) carrying hairpins as signaling molecules that respond to variation in tempearture. In view of the above teachings one of ordinary skill in the art can logically reach the conclusion that instead of using pH titration as taught by Chee et al, one can use increasing temperature (as taught

by Bonnet et al) as a decoding scheme. The advantages of using such a scheme is explicitly provided by Chee at al. state "one drawback with the previous system (system of decoding---added by Examiner) is that it requires a set of unique optical signatures. While large sets of such signatures are available, ----, it would be preferable to use decoding systems that do not relay on the use of sets of optical signatures. Accordingly, it is an object of the invention to provide methods to allow decoding of bead arrays without relying solely on unique optical signatures" (see page 4, lines 10-15)

Conclusion

11. All claims under consideration 17-37 are rejected over prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

TERESA E. STRZELECKA, PH.D.
PRIMARY EXAMINER

Teresa Strzelecka

6/25/07